APPENDIX II

Background of the Invention

This invention relates to an ankle foot orthosis intended to support the lower leg, ankle and foot. Such an orthosis may be required in order to counteract the effects of muscular and nervous disorders.

Summary of the Invention

Conventional orthoses provide a rather rigid strut or frame which is fixed to the lower leg and foot in order to counter the effect of e.g. muscle spasms therein. When fitted, the patient may be able to walk whereas without an orthosis, walking may be almost impossible.

A traditional orthosis is somewhat bulky, and may require the wearing of special clothing and shoes. An additional and significant disadvantage is that a normal walking gait cannot be obtained due to the inevitable immobilisation of at least part of the ankle joint.

WO-A-9834572 proposes an ankle/foot orthosis having a rigid strut connecting a lower leg support to a sole plate. The strut is generally inflexible, but the sole plate is said to have sufficient flexibility to improve the walking gait by permitting bending of the toes.

According to the present invention there is provided an ankle/foot orthosis comprising a strapping member for a lower leg, and having an inflexible anterior longitudinal stiffener, a sole

plate, and a relatively flexible strut connecting the longitudinal stiffener and the sole plate, the strut extending to the sole plate at the outer side thereof, and anterior of the position of the ankle.

Such an orthosis is flexible in the region of the ankle, and thus permits a degree of ankle flexibility, which promotes a more normal walking gait.

In this specification the terms flexible and inflexible are relative, and will be understood by the skilled man in relation to ankle/foot orthoses. Generally speaking, a flexible member has the degree of flexibility imparted by glass reinforced plastic resin (grp), whereas an inflexible member has the degree of flexibility imparted by a carbon fibre reinforced plastic resin. In terms of ankle movement, an inflexible member would prevent any substantial ankle movement in the plane or planes intended to be rigidified, whereas a flexible member would permit a degree of movement.

Preferably the flexible portions of the orthosis are manufactured substantially of glass fibre or aramid fibre reinforced resin, and the rigid portion is manufactured in carbon fibre reinforced resin. Such a construction permits integration of the fibres during the lay-up stage of manufacture, thus giving a substantially seamless resilient product after curing.

The rigidity of sole plate is preferably variable over the area thereof, portions being relatively rigid, and portions being relatively flexible so as to give support to the foot whilst allowing bending of the toes.

The strapping member preferably extends around the sides of the leg and has securing straps to accommodate variation in leg thickness. Preferably this strapping member is moulded from a

soft thermoplastic so as to be mouldable by application of heat. Thermoplastic also facilitates easy trimming to fit a patient, for example by scissors.

The flexible strut is preferably encased for protection against impact damage, and to reduce abrasion. The encasement may be a sleeve of plastics material, which is preferably heat shrinkable so as to mould itself tightly to the contours of the strut.

Fasteners may be provided whereby the stiffener is movable longitudinally of the strapping member, so as to facilitate comfortable fitment to persons of different leg length.

The stiffener is preferably on the inside of the strapping member, and in a preferred embodiment resides in a channel formed therein. The channel is preferably open at the bottom.

Brief Description of the Drawings

Other features of the invention will be apparent from the following description of a preferred embodiment, shown by way of example only in the accompany drawings in which:

Figure 1 is a side elevation of the lower leg and foot of a human, to which an orthosis according to the invention has been attached;

Figure 2 is a front elevation of an unattached orthosis corresponding to Figure 1; and

Figure 3 is a graphical representation showing the gait provided by the invention.

Detailed Description of the Drawings

With reference to the drawings, an orthosis 10 comprises a strapping member 11 of thermoplastic and typically having a thickness of 2.5mm. This member is sufficiently rigid to be self-supporting in a shape conforming approximately to the front and side contours of a human leg 12. The member is also mouldable by the application of heat, for example from a hot air gun, in order to obtain a good fit around a patient's leg. The sides of the supporting member are cut away to improve comfort, leaving four strapping regions which extend further round the leg. On the left side of Figure 2 (as viewed) simple buckles 13 are attached by fabric loops 14 and rivets 15. On the right side, fabric straps 16 having inner end and outer end areas 17, 18 covered with the different components of a suitable hook and loop type of fastener. The straps 16 are also attached by rivets 15.

Moulded within the member 11 is a channel 19 open at the bottom and generally aligned with the shin bone.

Closely fitting within the channel 19 is a stiffener 21 of carbon fibre reinforced resin. Typically the stiffener has a width of about 26mm, and a thickness of 3mm.

From the base of the stiffener 21 extends a strut 22 to which is provided a sole plate 23. Both the strut and the sole plate are of glass fibre reinforced resin, but the sole plate may include aramid or carbon fibres in order to improve the toughness and rigidity of selected areas. In particular the mid-region of the sole plate may be rather inflexible whereas the toe and heel regions may be relatively flexible so as to improve the gait of a wearer. Flexibility of the sole plate may be varied by changing the direction of reinforcement fibres. The periphery of the sole plate may be

solely of glass fibre to permit relatively easy trimming to size thereof.

The strut 22 is about 3mm thick at the ends, and has a circular section of about 8mm diameter in the mid-region. The change of strut section is smooth and the ends of the strut are smoothly radiussed into the stiffener and sole plate. During lay-up of the orthosis the fibres are integrated and overlapped to provide an essentially seamless construction.

The sole plate can be of any suitable shape, and typically has a thickness of 0.3-2.0mm.

The stiffener 21 is fixed to the strapping member 22 by rivets or screws 24. A plurality of fixing positions may be provided to allow adjustment for length of leg, for example a slot may be provided in the strapping member to allow for adjustment prior to permanent attachment.

Manufacture of the orthosis is by moulding the stiffener, strut and sole plate as a unit, the fibres being laid up in a mould or cut from pre-preg sheet. After curing, this component is trimmed to size if necessary. Trimming may be cosmetic, or can be used to influence the degree of flexibility imparted by the strut 22.

Thereafter the strapping portion is attached, after suitable measurement of a patient. Final fitting includes trimming of the sole plate, and moulding or trimming of the strapping portion.

To attach the orthosis, straps 16 are passed through the buckles 13, and the portions 18 laid over the portions 17 to the required degree of tightness. The straps 16 may finally be trimmed to a reasonable length.

Figure 3 shows a graphical representation of the gait of a typical wearer of the preferred embodiment. The 'X' axis shows time in seconds, and the 'Y' axis shows percentage of body weight. This gait approximates closely to a normal gait, the first peak indicating a distinct heel strike, and the second peak indicating a distinct toe strike. The forces generated approach those of a normal gait thus giving the user the appearance of walking normally. The overall time for a step at normal walking pace is about the same as for an undisabled person, thus permitting an approximately even walking pace where only one leg of the person requires support.

Various modification to the embodiment will occur to the skilled man within the scope of the appended claims and without departing from the essence of the present invention.

Abstract

An ankle/foot orthosis has a strapping member for the lower leg, an inflexible anterior longitudinal stiffener, a sole plate, and a relatively flexible strut connecting the stiffener to the sole plate. The flexible strut permits a degree of ankle flexibility, and promotes a more natural walking gait.